IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Application of: | Docket No.: 30900-CNT2 |
| HORNACK et al. | Group Art Unit No.: 1651 |
| Serial No.: 10/679,535 | Confirmation No.: 3990 |
| Filed: October 3, 2003 | Customer No.: 23589 |
| DIETARY SUPPLEMENT CONTAINING ALKALINE ELECTROLYTE BUFFERS | Examiner: Davis, Ruth A. |

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

## APPELLANT'S SECOND SUBSTITUTE BRIEF ON APPEAL

In response to the Office Action of October 10, 2006, and the Final Rejection of November 17, 2005, Appellant's Second Substitute Brief on Appeal in accordance with 37 C.F.R. § 41.37 is hereby submitted. The Examiner's Final Rejection of claims 1, 2, 7, and 14-18 is herein appealed, and allowance of said claims is respectfully requested. An Amendment After Final Rejection has been submitted asking that claims 5 and 10 be canceled.

The requisite fee of $250.00 as required by 37 C.F.R. § 41.20 has previously been submitted. Any additional fee due in accordance with this appeal should be applied against Deposit Account No. 19-0522.

Respectfully submitted,

Date: 12/5/06

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Following are the requisite statements under 37 C.F.R. § 41.37:

## I. Real Parties of Interest

Janmarie Hornack and Lawrence E. Dorman are the named co-inventors of the subject matter of this application. Mr. Dorman assigned his interest in the invention and application to Janmarie Hornack. Accordingly, Janmarie Hornack is the real party in interest, as she has not assigned her right to any other entity.

## II. Related Appeals and Interferences

No related appeals or interferences are known to Applicants that may directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

## III. Status of Claims

This appeal is of the final rejection of claims 1, 2, 7, and 14-18. Claims 3, 4, 5, 6, 8, 9, and 10 have been canceled.

The Office Action Summary in the Office Action of November 17, 2005, under Disposition of Claims, stated that claims 1, 2, 5, 7, 10, 14-18 were rejected. Item 5 indicated that claim 19 was allowable.

## IV. Status of Amendments

Appellants have submitted an Amendment After Final Rejection directing that claims 5 and 10 be canceled. It is submitted that the Amendment After Final Rejection should be entered in this case as placing the application in better condition for appeal by simplification of issues.

## V. Summary of the Claimed Subject Matter

### A. *Claim 1 (Independent)*

| **Claimed Subject Matter** | **Page and Line Number Support in Specification** |
|---|---|
| An improved alkaline dietary and/or therapeutic supplement composition consisting essentially of a | p. 1, ll. 11-12 |
| solid dietary and/or therapeutic supplement agent | p. 4, l. 7; p. 8, l. 10; p. 14, l. 3 |
| selected from a specific group of supplements known to promote health and well-being | p. 1, ll. 16-17 |
| and each having an initial pH of 6 or less, | p. 18, ll. 1-12 |
| which upon ingestion with food or beverage, would limit availability of the age to the person ingesting the agent. | p. 1, ll. 12-14; p. 5, ll. 4-5 |
| The supplement agent is combined with at least about 8% by weight of particular calcium, magnesium, or potassium alkaline electrolyte additives with the amount of the alkaline additive being sufficient to raise the pH of the combination to a level of from about 8 to about 12.5 | p. 8, ll. 16-18; p. 14, ll. 3-10 (calculation) |
| to cause rapid extracellular, intercellular, and intracellular movement of the agent into all cell structures of the person's body. | p. 5, ll. 17-19 |
| The presence of the alkaline electrolyte additive increases the effectiveness and functional utilization of the supplement agent while the alkaline composition is in the person's stomach. | p. 25, ll. 5-7 |

B. *Claim 2 (Dependent from Claim 1)*

A sufficient amount of the alkaline electrolyte is included in the composition to cause the pH thereof to be in the range of about 8 to about 10.5 (p. 8, ll. 17-18).

C. *Claim 16 (Independent)*

This claim contains the limitations of claim 1, but limits the supplement agent to solid glucosamine (p. 10, ll. 9 et seq.).

D. *Claim 5 (Dependent from Claim 16) – Appeal withdrawn; claim has been canceled.*

E. *Claim 14 (Independent)*

This claim contains the limitations of claim 1, but limits the supplement agent to methylsulfonylmethane (p. 10, ll. 9, et seq.).

F. *Claim 7 (Dependent from Claim 14)*

The supplement agent includes ascorbic acid (p. 16, l. 10).

G. *Claim 10 (Dependent from Claim 14) – Appeal withdrawn; claim has been canceled*

H. *Claim 15 (Dependent from Claim 14)*

The supplement agent includes a bioflavenoid (p. 16, l. 10).

I. *Claim 17 (Dependent from Claim 15 [sic Claim 16])*

The supplement agent includes methylsulfonylmethane (p. 10, ll. 9; p. 12, ll. 15, et seq.).

J. *Claim 18 (Independent)*

Calls for the combination of methylsulfonylmethane, ascorbic acid, bioflavenoid, and a sufficient amount of calcium carbonate, potassium gluconate, and magnesium oxide to provide for increased bioavailability and effectiveness of the supplement agents (p. 15, ll. 18-22; p. 16, ll. 1-8).

## VI. Grounds of Rejection to be Reviewed On Appeal

A. Can the Examiner's final rejection of claims 1, 14, and 16 under 35 U.S.C. § 112 ¶1 as failing to comply with the written description requirement, and final rejection of claims 1, 2, 7, and 14-17 under 35 U.S.C. § 112 ¶2 as being indefinite for failure to particularly point out and distinctly claim the subject matter which applicants regarded as their invention, be sustained?

B. Can the Examiner's final rejection of claims 1, 2, 7, 14, and 15 under 35 U.S.C. §§ 102(b)/103(a) as being anticipated by or obvious over Herschler U.S. Patent No. 4,568,547 be sustained?

C. Can the Examiner's final rejection of claims 1 and 2 under 35 U.S.C. §§ 102(b)/ 103(a) as being anticipated by or obvious over Stroppolo et al. U.S. Patent No. 5,693,312 be sustained?

D. Can the Examiner's final rejection of claims 1 and 2 under 35 U.S.C. § 103(a) as being unpatentable over the '547 Herschler patent be sustained?

E. Can the Examiner's final rejection of claims 16 and 17 under 35 U.S.C. § 103(a) as being unpatentable over Herschler U.S. Patent No. 4,616,039, Lysaght U.S. Patent No. 4,387,093, and Schinitsky U.S. Patent No. 4,473,551 be sustained?

F. Can the Examiner's Final Rejection of claim 18 under 35 U.S.C. § 103a as unpatentable over Herschler U.S. Patent 4,568,547 be sustained?

## VII. Arguments

### A. *The Law*

It has long been the law that "[d]uring patent examination the PTO bears the initial burden of presenting a *prima facie* case of unpatentability." *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984); *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993); *In re Rouffet*, 149 F.3d 1350, 1355, 47 USPQ2d 1453, 1455 (Fed. Cir. 1998); and *MPEP*, 2142, citing cases.

As explained in 2141 MPEP, the Office is required to follow the guidelines of *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 49 (1966), in which the court said that under § 103, the scope and content of the prior art are to be determined, the differences between the prior art and the claims at issue are to be ascertained, and the level of ordinary skill in the pertinent art resolved.

When applying § 103, (A) the claimed invention must be considered as a whole; (B) the references cited must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; ©) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) reasonable expectation of success is the standard with which obviousness is determined. *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. 1986) (MPEP 2141).

In determining the differences between the prior art and the claimed subject matter, the question is not whether the individual differences would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1513, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782 218 USPQ 698 (Fed. Cir. 1983). Prior art references must be considered in their entirety, as a whole, including portions that teach away from the claimed invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983) (cert. den. 469 U.S. 851 (1984)).

A reference relied upon by the Examiner in rejecting an applicant's claims must be in analogous prior art. That art must relate to matter that would logically have commended itself to an inventor's attention in considering the problem addressed. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993); *State Contracting Eng'g Corp. v. Condotte America, Inc.*, 346 F.3d 1057, 1069, 68 USPQ2d 1481, 1490 (Fed. Cir. 2003)

Factors that may be considered in determining the level of ordinary skill in the relevant art are explained in *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696, 218 USPQ 865, 868 (Fed. Cir. 1983) (cert. den. 464 U.S. 1043 (1984)).

## B. *Application of the Graham Guidelines*

### 1. Scope and Content of the Prior Art

#### a. Herschler U.S. Patent No. 4,568,547

Methylsulfonylmethane (MSM) is described as being useful as a tableting and granulating aid for pharmaceutically active agents, especially those which are unstable in the presence of moisture. Other conventionally pharmaceutically acceptable fillers may be incorporated in the tablets, "*in minor amounts, e.g., up to about 5% by weight. ...* Examples of such optionally present materials include inorganic salts, e.g., $CaCO_3$ ..." (Col. 4, ll. 62-66.) EXAMPLES III-VII include magnesium oxide, which is not readily soluble in the person's stomach and is not one of the alkaline electrolyte additives called for in the claims of this application. The footnotes to EXAMPLES III-VI make reference to potassium bicarbonate, but the amount of the bicarbonate, if present, is not specified. (Col. 10, ll. 37-68; col. 11, ll. 1-55.) EXAMPLE IX referred to by the Examiner in the

Final Rejection, page 6, describes a timed release tablet containing 250 mg of MSM, 250 mg of Vitamin C, 25 mg of potassium bicarbonate, 20 mg of glycine, and 10 mg of magnesium stearate; therefore the potassium bicarbonate is 4.7% by weight of the composition. The tablet described in EXAMPLE XI, also referred to on page 6 of the Final Rejection, does not contain an alkaline electrolyte.

### b. Stroppolo et al. U.S. Patent No. 5,693,312

This patent discloses pharmaceutical compositions containing (S)-2-(6-methoxy-2-naphthyl)-propionic acid (Naproxen) and arginine. Patent No. 4,834,966 referenced in the background section of the '312 patent, describes ibuprofen water-soluble compositions containing 33-46% by weight of ibuprofen, 34-51% by weight of L-arginine, and 9-29% by weight of sodium bicarbonate, which is said to increase the onset time of the analgesic effect of the ibuprofen. Stroppolo says that the pH value of the aqueous solution is due to the presence of arginine and therefore when arginine is in a molar excess, the addition of an auxiliary basic substance may not be necessary. (ABS; col. 1, ll. 45-51; col. 2, ll. 29-33; col. 3, ll. 35-67; col. 4, all; col. 5, all; col. 6, ll. 1-18.)

In the Examples of the patent, only sodium bicarbonate is referred to as an additive to be included with the Naproxen and arginine. A sodium composition is not a desirable agent for inclusion in the present composition and is excluded by the limitations of the rejected claims.

### c. Lysaght U.S. Patent No. 4,387,093

The arthritis treatment composition comprises cyanocobalamine ($B_{12}$), potassium iodide, magnesium sulphate, and ferrous sulphate. $B_{12}$ contains cobalt. A typical tablet or capsule comprises 125 mg of cobalt chloride, 250 mg of potassium iodide, 200 mg of calcium carbonate, 125 mg of magnesium sulphate, and 125 mg of ferrous sulphate. $B_{12}$ or some other cobalt compound may be used in place of cobalt chloride. (ABS; col. 1, ll. 26-30; col. 2, ll. 24-30, 37-39.)

The cobalt is said to halt the growth of arthritis and relieve pain. The iodide salt acts to relieve stiffness and bring back mobility to joints, the calcium carbonate serves as a bone strengthener and counteracts nausea caused by reaction of the solution with stomach acids, the magnesium sulphate acts as an anti-inflammatory agent to reduce pain, and the ferrous sulphate aids in regeneration of red blood corpuscles. The cobalt is said to be the vital and most important feature of the mixture. (Col. 1, ll. 48-61.)

Lysaght's composition is designed to cause the $B_{12}$ to pass through and not be digested in the stomach and to be received in the intestine.

### d. Herschler U.S. Patent No. 4,616,039

The '039 patent, a continuation in part of the Herschler application that issued as the '547 patent, relates to a method of supplementing naturally occurring MSM in a person's body to at least 1 ppm. (Col. 3, ll. 12-20.) Preferably, MSM is added to processed foods after processing has been completed and to heated foods immediately after serving. (Col. 5, ll. 67-68; col. 6, l. 1.) MSM may also be included in non-food products such as tobacco, which is said to enhance the flavor and taste of the smoke. (Col. 6, ll. 19-26.) The method as summarized in claim 1 comprises adding MSM to foodstuffs ingested daily by an animal to provide an amount equal to at least 0.01 mg/kg of body weight per day.

e. Schinitsky U.S. Patent No. 4,473,551

A method is disclosed of treating arthritis and other disorders having an inflammatory component comprising administering to the patent a synergistic therapeutic dose of shark cartilage and glucosamine in a weight proportion between about 5:1 and about 1:5. (ABS; Col. 2, ll. 57-66.)

2. Differences Between the Prior Art and the Claimed Subject Matter

Applicants discovered that by adding at least about 8% of a selected alkaline potassium, calcium, or magnesium electrolyte to acidic solid dietary and/or therapeutic supplement agents having a pH of 6 or less to increase the pH of the combination to a level such that the pH of the supplement is at an ideal pH of about 8 to about 12.5, a composition thus formulated results in at least two synergistic phenomena occurring. The subject matter of the appealed claims, which call for this unique synergistic combination, is not taught or suggested by the prior art of record relied upon by the Examiner in the Final Rejection.

First, the agent in the composition is more absorbable and more rapidly and efficiently digested in the cardio fundic portion of the individual's stomach. The majority of the agent is digested within a shorter time with less pH fluctuation caused by the composition ingested than would otherwise be the case, if the agent remained acidic. Second, incorporation of a critical amount of the electrolyte factors in the composition provides for an improved intracellular/extracellular transfer rate of the dietary and/or therapeutic supplement agent, contributing to the increased bioavailability and effectiveness of the supplement agent.

a. Herschler '547 is concerned with the utilization of MSM as a carrier or asserted adjuvant for solid pharmaceutical agents. Calcium carbonate may be added as a tableting agent. $CaCO_3$ is the only alkaline electrolyte disclosed in the '547 patent that is a component as called for the appealed claims. However, Herschler does not teach that a sufficient quantity of the calcium carbonate should be added to increase the pH of the pharmaceutical composition to about 8 to about 12.5, and makes no suggestion that the amount of the calcium carbonate should be at least about 8%. In fact, Herschler says the optional tableting agent, such as calcium carbonate, is present in only a minor amount, for example up to 5% by weight. Therefore, Herschler does not teach applicants' combination of at least 8% of an alkaline electrolyte combined with the claimed acidic supplement agents, with the amount of electrolyte added being sufficient to increase the pH of the aggregate composition to a level of from about 8 to about 12.5.

b. Stroppolo '312 adds sodium or potassium bicarbonate to a mixture of Naproxen and arginine as a tableting agent. There is no teaching in the Stroppolo reference of combining a supplement agent selected from the group consisting of water soluble acidic vitamins, bioflavenoids, minerals, trace minerals, whole plant food products containing phytonutrients, herbs, and mixtures of the foregoing, each of which has an initial pH of 6 or less, with at least about 8% of an alkaline electrolyte additive to bring the aggregate initial pH of the agent to about 8 to about 12.5. The amino acid side chains of arginine have a pH of 12.5; arginine is not an agent having an initial pH of 6 or less. Thus, the Stroppolo patent, which relates to a pharmaceutical composition consisting of Naproxen, a medicament not within the call of the appealed claims, and arginine, also outside of the call of the claims because among other things it is basic (see Exhibit G attached) rather than having a pH of 6 or less, is clearly non-analogous art. One skilled in the art would not look to Stroppolo for a solution to the problem addressed by the present invention of increasing the bioavailability in an individual's stomach of the specified supplement agents.

c. Lysaght '093 relates to a method of treating arthritis by administering a cobalt compound such as cyanocobalamin ($B_{12}$), combined with tableting agents such as calcium carbonate, magnesium sulfate, and ferrous sulfate. Other materials may be added, such as additional vitamins. The patentee seeks to assure that the formulation passes through the stomach into the intestines where the $B_{12}$ is effective. Thus, Lysaght also fails to suggest adding at least 8% by weight of an alkaline electrolyte to the specified acidic supplement agents, with at least a sufficient amount of the electrolyte being added to bring the pH of the composition to a level of about 8 to about 12.5.

d. Schinitsky '551 also seeks to treat arthritis ailments by providing a composition that combines cartilage, such as shark cartilage powder, with glucosamine. Schinitsky does not teach adding an alkaline electrolyte to his shark cartilage glucosamine medicaments.

e. Herschler '039 teaches only that MSM is useful as an additive to be incorporated in foods and has no relationship to the claimed subject matter of this application.

### 3. Level of Skill in the Art

The skilled artisan in this field is a person that has some academic knowledge and/or practical experience in the development, production and marketing of dietary and/or therapeutic supplement agents, and the pharmacology of such agents.

## C. *35 U.S.C. § 112 Rejections*

### 1. 35 U.S.C. § 112 ¶1

Appealed claims 1, 14, and 16 were rejected under 35 U.S.C. § 112 ¶1 as failing to comply with the written description requirement. The Examiner asserted that the recitation "at least 8% by weight" of the alkaline electrolyte is not disclosed in the specification as originally filed, and that the recitation could not be reasonably extrapolated from the disclosure. Applicants traverse this rejection because in the example on page 14 of the description, the alkaline electrolytes are about 8% of the formulation. In the example at the bottom of page 15 and the top of page 16, the alkaline electrolytes are about 11% of the formulation. The claims state that a sufficient amount of alkaline electrolyte are added to increase the pH of the composition to a pH of about 8 to about 12.5. Those skilled in the art can readily determine how much of the electrolyte must be added to a particular supplement agent composition in order to obtain a pH within the specified range of 8 to about 12.5. pH measurements and the equipment for making pH measurements are well known and would not require experimentation to determine a pH of a particular composition. Thus, finite limits are placed on the alkaline electrolyte, at least about 8% and no more than the amount required to bring the pH of the final composition to an upper pH level of about 12.5.

### 2. 35 U.S.C. § 112 ¶2

Appealed claims 1, 2, 7, and 14-17 were rejected under 35 U.S.C. § 112 ¶2 as being indefinite because it is asserted the claims are unclear as to whether the referenced anions are a part of the calcium, magnesium, and potassium cations. The claims are in the form of the specification. On page 9, line 19, the alkaline electrolytes are described as being calcium, magnesium, and potassium [cations], while at lines 23-25 of page 14, the specific anions are disclosed for "respective alkaline minerals as described above." The Examiner's objection is hyper-technical. However, the claims can be amended under 37 C.F.R. § 312 to recite respective cations before each anion, should the Board so stipulate in order to overcome the asserted indefiniteness.

### D. *The Rejections of the Claims Are Based on Mere Conjecture, Speculation and Unsupported Assumptions*

Recognizing that the cited references are deficient in major respects, the Examiner has resorted to conjecture, speculation, and unsupported assumptions as to what the references in fact teach. Exemplary are the assertions that the claimed functional attributes of the present claimed invention "*would be inherent* in the reference composition[s]," "it would *appear* that the reference composition[s] *must* also function in the manner instantly claimed" and that the compositions of the references "would also *appear* to exhibit the claimed functional characteristics." The Examiner therefore concludes, notwithstanding the acknowledged deficiencies of each of the references relied upon, the claimed invention is anticipated or is obvious from the cited patents.

"Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re: Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

"In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics *necessarily* flows from the teachings of the applied prior art." *Ex Parte Levey*, 17 USPQ2d 1461, 1464 (Bd. App. & Inter. 1990).

### E. *35 U.S.C. § 102/103 Rejections*

#### 1. Claims 1, 2, 7, 14, and 15 anticipated or obvious over Herschler '547

It is asserted that the `547 Herschler patent teaches the combination of methylsulfonylmethane (MSM) with ascorbic acid and bioflavonoids. The Examiner acknowledges that the reference does not teach:

(1) that the therapeutic agents have a pH of 6 or less;

(2) that the therapeutic agents have limited availability because the pH of each is 6 or less; and

(3) that the provision of sufficient alkaline electrolyte additive to raise the pH of the composition to about 8 to about 12.5 improves the effectiveness of the composition in the stomach.

First, Herschler states that a minor amount of calcium carbonate may optionally be added as a tableting agent, "e.g., up to about 5% by weight." (Col. 4, ll. 63-65.) There is no direct or implied disclosure in Herschler of incorporating a sufficient amount of an alkaline electrolyte additive in his pharmaceutical agent that includes MSM to increase the pH of the agent to a level of from about 8 to about 12.5. Moreover, applicant's composition contains more that 5% of the alkaline electrolyte. The remaining claims were amended to recite that the alkaline agent is present at a level of at least about 8% by weight of the composition, well above the 5% ceiling of Herschler. Support for the at least about 8% recitation is found in the Example at page 14 (1800 mg. of the agent and 150 mg. of the alkaline electrolyte, i.e., 8.3% electrolyte) and the Example at pages 15 and 16 (1800 mg. of the agent and 200 mg. of the alkaline electrolyte, i.e., 11.1% electrolyte). The upper limit of the alkaline electrolyte is established by the limitation calling for addition of a sufficient amount of the electrolyte to increase the pH of the composition to a pH level of about 12.5. This is a finite amount and can readily be determined using conventional pH measuring techniques and equipment.

Herschler incorporates a small amount of calcium carbonate in his MSM formulation only as a filler or a tableting agent, not to enhance the effectiveness and functionality of the MSM in the person's body, and especially absorption of the agent in the individual's stomach. Herschler does not suggest incorporating an amount of an alkaline electrolyte additive to the formulation that is sufficient based on the aggregate initial pH of the agent to raise the pH of the combination of the supplement agent and the additive to a pH from about 8 to about 12.5 to cause rapid extracellular, intercellular, and intracellular movement of the agent into all cell structures of the person's body.

The Examiner has argued that because the ingredients of the Herschler formulations are the same as set forth in claims 1, 2, 7, 14, and 15, the compositions would inherently function in the same manner as applicants' compositions. Herschler relates to the asserted advantage of utilizing MSM as a carrier or adjuvant for solid pharmaceutical compositions. Herschler does not teach that the pharmaceutical agents have a pH of 6 or less, or that a specified alkaline electrolyte should be added to the supplement agent with the amount of electrolyte being from about 8% to an amount sufficient to increase the pH of the composition to a pH of from about 8 to about 12.5. Consequently, the formulations of the Herschler patent cannot and would not inherently function in the same manner as the functionality of the claimed composition. It is the constituents identified in the claims and the claimed proportions of those constituents that give applicants their improved, unique, unexpected, and unobvious results.

The Examiner asserts on page 6 of the Office Action that Herschler teaches 10% of the electrolytes in examples IX and XI, which is"at least 8%" as explained. In EXAMPLE IX, 25 mg of potassium bicarbonate is combined with 250 mg of MSM, 250 mg of Vitamin C, 20 mg of glycine, and 10 mg of magnesium stearate. The potassium bicarbonate is only 4.7% of the formulation, which is in accord with the "up to about 5%" limitation set forth in column 4 at line 65 of the Herschler patent. In EXAMPLE XI, the calcium stearate, which is not one of the alkaline electrolytes called for by the appealed claims, is present in an amount no more than about 5%, also within Herschler's "up to about 5%" ceiling.

Because there is no disclosure within the four corners of Herschler of the combination called for in the appealed claims, Herschler cannot be found to anticipate the claims. Furthermore, there would be no motivation or suggestion, based on the teachings of Herschler, for one skilled in the art (using the criteria of *Environmental Designs*) to select supplement agents specifically called for in the appealed claims that have a pH of 6 or less, and to then add a greater amount of the alkaline electrolyte than taught by Herschler to increase the pH of the supplement agent to the specified level of about 8 to about 12.5. Accordingly, the subject matter of claims 1, 2, 7, 14, and 15 is not obvious in view of Herschler.

### 2. Claims 1 and 2 anticipated or obvious over Stroppolo '312

The Stroppolo patent is concerned with combining arginine with Naproxen. Arginine is said to hasten the analgesic effect of the active drug and improve its lasting effect. Sodium or potassium bicarbonate is optionally added to the formulation as an effervescent agent so that if the product is dissolved in water, the resultant aqueous solution has a pH from 7.5 to 9. Furthermore, the sodium or potassium bicarbonate is said to improve the rheological characteristics of the mixture making it particularly suitable for granulation and then compression into a tablet.

The supplement composition as set forth in the remaining claims of this application consists essentially of an agent selected from the group consisting of water soluble vitamins, bioflavonoids, minerals, trace minerals, phytonutrients, and herbs, all of which have initial pH of 6 or less. Arginine, an essential amino acid, is not in the class of agents called for by the present claims, but is an essential component of Stroppolo's formulation. The "consisting essentially of" format of the claims of this application rules out the inclusion of an amino acid such as arginine.

As is the case with the rejection based on the `547 Herschler patent, the Examiner acknowledges that Stroppolo does not teach that the effectiveness and functional utilization of therapeutic agents having a pH of 6 or less and therefore of limited availability can be significantly enhanced by using the aggregate pH of the therapeutic agent as a basis for determining how much alkaline electrolyte should be added to the therapeutic agent to bring the pH of the combination to a pH of 8 to 12.5. By doing so, absorption of the composition occurs rapidly and efficiently in the person's stomach rather than in the individual's intestines to cause rapid extracellular, intracellular and intercellular movement of the agent into all cell structures of the person's body.

Stroppolo therefore within its four corners does not teach that supplement agents as called for by claims 1 and 2 having an initial pH below 6 should be combined with a sufficient amount of an alkaline electrolyte as specified to increase the pH of the composition to a pH of from about 8 to about 12.5. Stroppolo does not anticipate claims 1 and 2. The Naproxen/arginine formulation of Stroppolo would not inherently perform the function that results from applicants' claimed compositions, not only because the ingredients are different, but because the proportions thereof are not the same.

The Examiner's conjecture, speculation, and unsupported assumptions regarding asserted inherency find no support in the disclosure of Stroppolo. The Examiner argues that although the ingredients are not the same and the proportions are not the same in the Stroppolo patent as compared with the constituents and their amounts as claimed, one skilled in the art could adjust the amounts of each ingredient as a matter of routine experimentation. The Examiner's assertion assumes that one skilled in the art would understand the goal to be accomplished by applicants' composition, that the constituents would perform the desired function, and that in order to do so, the constituents would have to be present in certain proportions and relationships. All of this requires proscribed hindsight based on the teachings of the present application and is contrary to reason and the law.

3. Claims 1, 2, and 8 [previously canceled] obvious over Herschler ’547

This rejection is redundant with the prior 102(b)/103(a) anticipation/obviousness rejection of claims 1 and 2, and therefore applicants’ earlier arguments re Herschler need not be repeated.

4. Claims 16 and 17 obvious over Herschler ’039, Lysaght ’093, and Schinitsky ’551

The supplement agent called for in appealed claim 16 is glucosamine having an initial pH of 6 or less. Claim 17, dependent from claim 16, adds that the agent includes a quantity of MSM, with the pH of the combination being less than 6.

The ’039 Herschler patent is relied upon by the Examiner only because it discloses an arthritis treatment composition based on MSM. Thus, the ’039 patent has no direct relevance to the combination called for in claims 16 and 17 of a supplement agent having an initial pH of 6 or less and a specified alkaline electrolyte additive that is present in an amount of at least about 8% with a sufficient amount of the electrolyte being provided to increase the pH of the combination to a pH of from about 8 to about 12.5.

The Lysaght ’093 patent is relied upon by the Examiner for its teaching of compositions for treating arthritis by administering a cobalt compound, preferably cyanocobalamin ($B_{12}$) along with potassium iodide, magnesium sulphate, and ferrous sulphate. A tablet may be provided consisting of cobalt chloride, potassium iodide, calcium carbonate, magnesium sulphate, and ferrous sulphate. The patentee asserts that the provision of a cobalt compound, such as cobalt chloride, is effective in alleviating the adverse effects of arthritis. Cobalt chloride, said to be a substitute for $B_{12}$ [known by those skilled in the art to have a neutral pH of about 7.16], is not one of the supplement agents called for in appealed claims 16 and 17.

The calcium carbonate that may be included in one of the patentee's formulations, "serves as a *bone strengthener*," and not as an electrolyte for raising the pH of an initially acidic defined supplement composition to a designated alkaline level of from about 8 to about 12.5. (See col. 1, ll. 51-52.)

Lysaght tailors his formulation so that it passes through the stomach into the small intestine to the ileum (end of the small intestine) where the formulation is finally absorbed, whereas in the present invention, the supplement agent and the electrolyte are absorbed in the individual's upper (cardio) stomach.

As explained in the attachments, Exhibits A- F (submitted with applicants' amendment of August 22, 2005), vitamin $B_{12}$ must bind with Intrinsic Factor, move through the stomach without absorption into the small intestine to the ileum, which is located at the lower end of the small intestine. $B_{12}$ is not absorbed in the stomach. Similarly, cobalt chloride would be absorbed in the intestine and, therefore, outside of the stomach.

Accordingly, for one skilled in the art to find a teaching in the Lysaght patent of the subject matter of the appealed claims in this application, that person would find it necessary to entirely eliminate the cobalt compound and provide only a mixture of calcium carbonate, magnesium sulphate, and ferrous sulphate. This evisceration of the Lysaght disclosure would render the patentee's formulation inoperative for its intended purposes, i.e., provide a treatment for arthritis. Lysaght is not a relevant and analogous reference to the subject matter of the appealed claims.

The Schinitsky patent was cited by the Examiner only because the patentee suggested that glucosamine is useful for treating arthritis. There is no disclosure or suggestion in Schinitsky of adding at least about 8% of an alkaline electrolyte to glucosamine to raise the pH of the composition to a pH of about 8 to about 12.5.

The Examiner's final rejection of claims 16 and 17, was based on the assertion that "no invention resides in combining old ingredients of known properties where the *results* obtained thereby are no more than the additive effect of the ingredients" (citing *In Re Sussman*, 1943 C.D. 518).

The Examiner's assertion that the subject matter of claims 16 and 17 would have been obvious to one skilled in the art from the combined teachings of Herschler '069, Lysaght, and Schinitsky, is based on an arbitrary selection of individual constituents from each patent using applicants' claims as a guide for such selection, while totally ignoring the requirements of the claims with respect to the proportions of the constituents. Specifically, Herschler teaches only that MSM should be added to food. One skilled in the art would find no suggestion in Herschler of adding an alkaline electrolyte to increase the pH to the specified level of about 8 to about 12.5. Lysaght's arthritis treatment requires a cobalt compound plus antacids to avoid destruction of the cobalt material in the person's stomach so that it will be available for absorption in the lower end of the individual's small intestine. Again, a person skilled in the art, reading the Lysaght patent, would not be led to eliminate the cobalt compound, leaving only the antacid components, if that person was seeking to solve the problems addressed by applicants' claimed invention. Schinitsky teaches only combining glucosamine with cartilage powder, such as shark cartilage. One skilled in the art, in considering the Schinitsky disclosure, would find no suggestion of eliminating the shark cartilage, considered by the patentee to be an essential ingredient, and to then add an alkaline electrolyte to increase the pH of the remaining glucosamine to a pH of about 8 about 12.5.

The Examiner criticized applicants' response to the first action in this case for its asserted reliance on functional results rather than difference in composition and proportions. In the final rejection, though, the Examiner seeks to rely upon alleged similar results of the cited prior art being no more than the additive effect of the ingredients. After-the-fact reconstruction of three different prior art references that have no relation one to the other, where component parts are dissected and picked out piecemeal, and proportion limitations are ignored as has been done by the Examiner in rejecting claims 16 and 17, finds no support in fact or law.

### 5. Claim 18 Is Patentable Over the '547 Herschler Patent

Claim 18 calls for an improved dietary and/or therapeutic supplement composition consisting essentially of 1,000 mg of MSM, 780 mg of ascorbic acid, 20 mg of bioflavenoid, 100 mg of calcium carbonate, 50 mg of potassium gluconate, and 50 mg of magnesium oxide. This therapeutic supplement composition has the beneficial properties explained in second full paragraph of Section 2 of applicants' main Brief under the heading Differences in the Prior Art and the Claimed Subject Matter. The agent in the composition, MSM, is more absorbable and more rapidly and efficiently digested in the cardio fundic portion of the individual's stomach and the majority of the agent is digested within a shorter time with less pH fluctuation, than would otherwise be the case as a result of the combination of MSM with the other constituents set forth in claim 18 in the relative proportions of each. The composition provides for improved intracellular, extracellular transfer rate of the MSM contributing to the increased bioavailability and effectiveness of the supplement agent.

Herschler utilizes MSM as a tableting agent for various ingredients. There is no teaching or suggestion in Herschler of the combination set forth in claim 18, or the relative proportions thereof.

Specifically, when the ingredients of the Examples of the '547 Herschler patent are compared with the claimed constituents of claim 18, it is clear that Herschler does not suggest or teach the claimed combination, and Herschler's formulations would not accomplish appellants' unique results. The only ingredients in Herschler's '547 Examples that correspond with constituents of claim 18 are as follows, with the amounts of the ingredients being totally different from the corresponding constituents of claim 18:

*Example I*
MSM – 50%
ascorbic acid – 48%

*Example II*
MSM – 50%
ascorbic acid – 50%

*TABLETING WITH MSM*
MSM
magnesium oxide
Vitamin C

*Example III*
MSM – 250 mg
Vitamin C – 250 mg
bioflavenoids – 5 mg
magnesium oxide – 50 mg

*Example IV*
MSM – 250 mg
Vitamin C – 60 mg
bioflavenoids – 5mg
magnesium oxide – 125 mg

*Example V*
MSM – 250 mg
Vitamin C – 60 mg
magnesium oxide – 100 mg

*Example VI*
MSM – 250 mg
Vitamin C – 60 mg
magnesium oxide – 127 mg

*Example VII*
MSM – 150 g
magnesium oxide – 100 g

*Example VIII*
MSM

*Example IX*
MSM – 250 mg
Vitamin C – 250 mg

*Example X*
MSM – 200 mg
Vitamin C – 200 mg

*Example XI*
MSM – 100 mg

*Example XII*
MSM – 0.290 g

*Example XIII*
MSM – 0.290 g

*Example XIV*
MSM – 250 mg
Vitamin C – 250 mg

*Example XV*
MSM – 200 mg
Vitamin C – 200 mg

*Example XVI*
MSM – 100 mg

It is clear from the foregoing that none of the Examples in the '547 patent disclose the combination of ingredients called for by claim 18 and there is no teaching of the relative proportions of the respective ingredients.

The argument at pages 12-14 of appellants' main Brief with respect to failure of the '547 patent to anticipate or render claims 1, 2, 7, 14, and 15 obvious, applies with equal force to claim 18 and is incorporated by reference thereto. Claim 18 is even more specific than claims 1, 2, 7, 14, and 15, and is clearly not anticipated or obvious from the '547 Herschler patent.

G. *Conclusion*

Claims 1, 2, 7, and 14-17 are clearly patentable over the cited art, and the Examiner's final rejection of these claims should be reversed.

Respectfully submitted,

Date: 12/5/06

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## VIII. Appealed Claims Appendix

1. An improved alkaline dietary and/or therapeutic supplement composition consisting essentially of, in combination:

a solid dietary and/or therapeutic supplement agent selected from the group consisting of water soluble acidic vitamins, bioflavonoids, minerals, trace minerals, whole plant food products containing phytonutrients, herbs, and mixtures of the foregoing that are known to promote health and well being and each having an initial pH of 6 or less which upon ingestion with food or a beverage would limit the availability of the agent to the person ingesting the agent; and

an alkaline electrolyte additive selected from the group consisting of calcium hydroxide, chloride, di-phosphate, carbonate, gluconate, bicarbonate, phosphate and sulfate, magnesium hydroxide, chloride, di-phosphate, carbonate, gluconate, bicarbonate, phosphate and sulfate, and potassium hydroxide, chloride, di-phosphate, carbonate, gluconate, bicarbonate, phosphate and sulfate electrolytes, at least about 8% by weight of the alkaline electrolyte additive being provided in combination with the agent, the amount of the alkaline electrolyte additive being sufficient based on the aggregate initial pH of the agent to raise the pH of the combination of the supplement agent and the additive to a pH of from about 8 to about 12.5 to cause rapid extracellular, intercellular, and intracellular movement of the agent into all cell structures of the person's body, such that upon ingestion of the alkaline composition with food or a beverage, the presence of the alkaline electrolyte additive increases the effectiveness and functional utilization of the supplement agent while the alkaline composition is in the person’s stomach.

2. An improved dietary and/or therapeutic supplement composition as set forth in claim 1, wherein a sufficient amount of said alkaline electrolyte additive is included in the composition to cause the pH thereof to be in the range of about 8 to about 10.5.

7. An improved dietary and/or therapeutic supplement composition as set forth in claim 14, wherein said supplement agent includes ascorbic acid.

14. An improved alkaline dietary and/or therapeutic supplement composition consisting essentially of, in combination:

a solid methylsulfonylmethane supplement agent having an initial pH of 6 or less which upon ingestion with food or a beverage would limit the availability of the agent to the person ingesting the agent; and

an alkaline electrolyte additive selected from the group consisting of calcium hydroxide, chloride, di-phosphate, carbonate, gluconate, bicarbonate, phosphate and sulfate, magnesium hydroxide, chloride, di-phosphate, carbonate, gluconate, bicarbonate, phosphate and sulfate, and potassium hydroxide, chloride, di-phosphate, carbonate, gluconate, bicarbonate, phosphate and sulfate electrolytes, at least about 8% by weight of the alkaline electrolyte additive being provided in combination with the agent, the amount of the alkaline electrolyte additive being sufficient based on the initial pH of the agent to raise the pH of the combination of the supplement agent and the additive to a pH of from about 8 to about 12.5 to cause rapid extracellular, intercellular, and intracellular movement of the agent into all cell structures of the person's body, such that upon ingestion of the alkaline composition with food or a beverage, the presence of the alkaline electrolyte additive increases the effectiveness and functional utilization of the supplement agent while the alkaline composition is in the person's stomach.

15. An improved alkaline dietary and/or therapeutic supplement composition as set forth in claim 14, wherein the supplement agent includes a quantity of a bioflavonoid, the combination of methylsulfonylmethane and bioflavonoid having an initial pH less than about 6, the amount of the alkaline electrolyte additive being sufficient based on the aggregate initial pH of the agent to raise the pH of the combination to said level of from about 8 to about 12.5.

16. An improved alkaline dietary and/or therapeutic supplement composition consisting essentially of, in combination:

a solid glucosamine supplement agent having an initial pH of 6 or less which upon ingestion with food or a beverage would limit the availability of the agent to the person ingesting the agent; and

an alkaline electrolyte additive selected from the group consisting of calcium hydroxide, chloride, di-phosphate, carbonate, gluconate, bicarbonate, phosphate and sulfate, magnesium hydroxide, chloride, di-phosphate, carbonate, gluconate, bicarbonate, phosphate and sulfate, and potassium hydroxide, chloride, di-phosphate, carbonate, gluconate, bicarbonate, phosphate and sulfate electrolytes, at least about 8% by weight of the alkaline electrolyte additive being provided in combination with the agent, the amount of the alkaline electrolyte additive being sufficient based on the initial pH of the agent to raise the pH of the combination of the supplement agent and the additive to a pH of from about 8 to about 12.5 to cause rapid extracellular, intercellular, and intracellular movement of the agent into all cell structures of the person's body, such that upon ingestion of the alkaline composition with food or a beverage, the presence of the alkaline electrolyte additive increases the effectiveness and functional utilization of the supplement agent while the alkaline composition is in the person’s stomach.

17. An improved alkaline dietary and/or therapeutic supplement composition as set forth in claim 15 wherein the agent includes a quantity of methylsulfonylmethane, the combination of glucosamine and methylsulfonylmethane having an initial pH less than about 6, the amount of the alkaline electrolyte additive being sufficient based on the aggregate initial pH of the agent to raise the pH of the combination to said level of from about 8 to about 12.5.

18. An improved alkaline dietary and/or therapeutic supplement composition wherein the composition consists essentially of an admixture of

1000 mg of methylsulfonylmethane (MSM);
780 mg of ascorbic acid;
20 mg of bioflavonoid;
100 mg of calcium carbonate;
50 mg of potassium gluconate; and
50 mg of magnesium oxide.

## IX. Evidence Appendix

Exhibit A: Notebook page – pH measurements

Exhibit B: Diagram of digestion

Exhibit C: Vitamin $B_{12}$ literature references

Exhibit D: *Handbook of Vitamins, Minerals and Hormones, Second Edition* (selected pages)

Exhibit E: Web pages re: Vitamin $B_{12}$

Exhibit F: *Textbook of Physiology, 21st Edition, Volume 2*, Patton, et al. (selected pages)

Exhibit G: Graph of amino acid side chain pK values

## X. Related Proceedings Appendix

There are no related proceedings.